

UNITED STATES
DEPARTMENT OF
AGRICULTURE

PLANT SANITATION
SANITATION REQUIREMENTS

Agricultural
Marketing
Service

Fruit and
Vegetable
Division

Processed
Products
Branch

File Code
159-A-1

July 1995

PREFACE

This handbook is issued under authority of the Regulations Governing Inspection and Certification of Processed Fruits and Vegetables and Related Products to provide Processed Products Branch policy and procedures regarding plant sanitation requirements established by the Department of Health and Human Services, Food and Drug Administration.

This issue of File Code 159-A-1, Plant Sanitation, Sanitation Requirements, supersedes the edition of the file code dated May 1982 and the following:

Branch Notice Number 2284, Plant Surveys - Can Cleaners, dated May 1983

File Code 159-B-3, Withdrawal of Service, dated May 1972

File Code 159-B-5, State Sanitation Requirements, dated March 1974

File Code 159-A-8, Sanitation in Food Products Manufacture, dated August 1961

File Code 159-B-20, Recommendations for Piping, Valves and Pumps; Handling Food Products, dated March 1964

Information concerning the Processed Products Branch sanitation program and other inspection and grading services provided by this Branch may be obtained from:

Chief, Processed Products Branch
Fruit and Vegetable Division, AMS
United States Department of Agriculture
P.O. Box 96456, Room 0726 - South Building
Washington, D.C. 20090-6456

Telephone: (202) 720-4693

Fax: (202) 690-1527

James R. Rodeheaver
Branch Chief

Distribution:A
Agriculture:Washington

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SECTION 1

SANITATION INSPECTION

I. GENERAL

In-plant inspection is designed to give the user maximum benefits in relation to the quality of product packed, condition of raw materials, in-process control, availability of inspection reports, and sanitation inspection. These benefits can be realized to the fullest extent only when good sanitary and good manufacturing practices exist. The Branch must maintain consumer confidence by observing principles that will assure that proper conditions exist in plants where inspectors are assigned.

Processors expect to receive the same treatment (uniform interpretation of regulations and instructions) as their competitors. Inspectors are given continual training so that adequate sanitation criteria are clearly understood and applied. Supervisors and inspectors will work with plant management to maintain high standards of sanitation.

The prerequisite for performing an efficient, thorough sanitation inspection is an intimate knowledge of the plant layout, premises, machinery, equipment, and process.

A. Plant Management's Role in Sanitation

The plant management has the responsibility to produce a clean product in a clean plant under sanitary conditions.

Each plant or department must have a trained employee responsible for sanitation. This responsibility must include an inspection of the plant or department to insure proper and effective cleanup prior to the start of operations and that it is maintained throughout the shift. An adequate cleanup depends on four things:

1. An effective cleanup procedure;
2. Trained, properly supervised personnel;
3. Cleanup equipment and materials; and
4. Time to properly accomplish the work.

B. Inspector's Role in Sanitation

One of the most important aspects of the inspector's job is that of sanitation. Both the plant management and the inspector have specific sanitation responsibilities which should not be assumed by the other. The plant management should not view the inspector as an additional foreman or a sanitation supervisor. The inspector should not feel his/her presence and influence is not needed in those plants or situations where a good sanitation program exists. The inspector must see that plant management assumes their responsibilities to produce a clean product in a clean plant.

The inspector must acquire a basic understanding of why good sanitation is essential. He/She should know the plant and its operational procedure. This includes the proper cleaning procedure. The inspector must look and be personally clean. He/She should always remember that they are dealing with a product used as human food.

This handbook is designed to help the inspector make good decisions based on sound reasoning and to apply the same sanitary standards with equal fairness to all plants. In addition, supervisors should be kept informed and contacted when there are areas of doubt or problems with which the inspector may need assistance.

II. PROCEDURES FOR MONITORING PLANT SANITATION

A. General

Inspectors have the responsibility of evaluating management's plant sanitation program to the extent necessary to assure that sanitation practices are satisfactory. They must continually be on the alert to help management's representative spot conditions that might contribute to product contamination.

Inspectors can use plant sanitation history as a guide for checking areas during the survey. Major or critical sanitation conditions can not be tolerated because there is not enough time to check the plant. When additional help is needed for adequate inspection coverage, the officer-in-charge should be notified immediately.

Plants operating on an "around-the-clock" basis may be reluctant to contribute operating time for the purpose of cleanup. Sanitation requirements cannot be maintained under these conditions.

Plants under in-plant inspection must periodically cease operations or portions of operations for a length of time necessary to maintain proper sanitation. The length of time required to maintain good conditions will depend on the size and efficiency of the cleanup crew and equipment, the size of the plant, complexity and accessibility of processing equipment, and the kind of product being processed.

Shutdown for cleanup must be supplemented by "sustaining" cleanup during operations and all recesses. The "sustaining" cleanup includes designated personnel to empty garbage containers, keep floors hosed off during operations, and to clean belts, fillers, cutters, and other similar equipment and facilities during recesses.

The plant layout may permit alternate shutdowns on one or more lines for cleanup while other lines of the same product continue processing operations. This type of cleanup **should not** be permitted if there is danger of adulterating product lines that are in operation.

B. Definition of Terms for Rating Conditions

1. **Minor Deficiencies** do not result in product contamination, but are not desirable.
2. **Major Deficiencies** may result in product contamination or are highly objectionable.
3. **Critical Deficiencies** result in product contamination.

C. Correction of Sanitary Deficiencies

1. **Minor Deficiencies** should be corrected within 24 hours or less if specified by the inspector.
2. **Major Deficiencies** must be corrected within the time specified by the inspector. This is normally between the time the deficiency is

discovered and the next shift or end of the next cleaning period, depending on the probability of product contamination.

3. **Critical Deficiencies** must be corrected immediately. Contaminated product not immediately disposed of must be placed in a "hold" category pending disposition.

D. Coverage of Exempt Product Lines

Processing lines or facilities producing product not covered by the in-plant inspection contract are to be maintained in a clean, sanitary condition. Deficiencies in facilities or housekeeping which may pose a hazard to product safety must be corrected. Inspector's concern will primarily be the general appearance of the facilities and operations as observed by a walk-through. A detailed sanitation inspection of the equipment is not normally necessary.

III. REPORTING SANITATION CONDITIONS

A. Oral Reports

The inspector will make an oral report to the designated plant "sanitarian" on any major or critical deficiencies at the time encountered. Inspectors will also take prompt action to warn plant management of situations which are in danger of deteriorating to an unsatisfactory condition, whenever possible. Oral reports will be confirmed in writing by using the appropriate sanitation score sheets.

B. Written Reports, Sanitation Score Sheets

1. Procedure

Sanitation score sheets are used to record and report the inspector's evaluations of plant sanitation to plant management. These evaluations are made on a pre-operational basis and during processing operations for each production shift covered by an inspector. Score sheets, when completed, should provide a summary of conditions for that production day. These continuing evaluations and reports will prove most beneficial to all concerned in quickly recognizing and correcting any troublesome areas. Evaluations of a positive nature are also very important so that plant management will be informed when certain corrective actions are

considered effective or when special efforts have been made to improve the overall appearance.

The score sheets, when used with the continuation sheet, provide sufficient space to clearly explain any deficiencies encountered and to indicate when and what corrective action was taken.

Exhibit 1 shows a completed example of form FV-416-1, "Sanitation Score Sheet for Canned Food Processing Plants." The applicable score sheet for (canned, frozen, citrus, olives, or raisins) is to be used in plants using our services. The inspector may use a similar form only after approval from the Branch Chief.

Exhibit 1 (CONT) shows a completed example of form FV-416-5, "Sanitation Score Sheet for Processing Plants (Continuation Sheet)."

2. Recording

Minor Conditions. Report as "MN" on the sanitation score sheet opposite the applicable item. If not corrected within the time specified by the inspector, the condition is considered "Unsatisfactory", and shown as "U."

Major Conditions. Report as "MJ" on the sanitation score sheet opposite the applicable item. If corrective action is not taken within the time specified by the inspector, prior to the next shift or at the end of the next cleanup period, it is considered "Unsatisfactory", and shown as "U."

Critical Conditions. Report as "CR" on the sanitation score sheet opposite the applicable item. Action taken on the contaminated product is noted.

Record deficiencies even when cleaned up immediately; however, note on the sanitation score sheet that corrective action was taken promptly.

3. Distribution of Sanitation Score Sheet

- a. Plant Management — original to the designated plant employee responsible for the sanitation program with copy(s) to upper-level management, as necessary.
- b. USDA Plant File — one copy.
- c. Area Field Office — one copy when conditions are "Unsatisfactory" or unusual. 1/
- d. Regional Office — one copy when conditions are "Unsatisfactory" or unusual. 1/
- e. National Office — one copy when conditions are "Unsatisfactory" or unusual. 1/

1/ Send such sanitation score sheets daily.

C. Problem Situations

The **Inspector** is responsible for informing the officer-in-charge of any sanitation problem situations in the plant, including instances of "no corrective action".

The **Officer-in-Charge** is responsible for informing the regional director of any particular plant that has a definite or potential sanitation problem. He/She will also initiate recommendations for withdrawal of service if the problem(s) can not be resolved after discussion with plant management.

The **Regional Director** will submit the recommendation of withdrawal (if he/she concurs with the officer-in-charge) to the Branch Chief. The withdrawal will proceed in accordance with File Code 175-B-76, "Rules of Practice Governing Withdrawal of Inspection and Grading Service Under the Agricultural Marketing Act of 1946." (7 CFR, Part 50.)

D. Recommendations for Handling Unsatisfactory Sanitation Conditions

- 1. The inspectors should be certain that all sanitation score sheets are distributed to plant management responsible for the sanitation program. The lines of communication must be kept open and clear so all unsatisfactory ratings can be discussed in detail.

2. If there are unsatisfactory sanitation reports for three successive days or three within one week, the inspector shall contact his/her supervisor. The supervisor shall contact the appropriate plant management, either by telephone or personal visit, and arrange for corrective action of the unsatisfactory plant conditions. **Pertinent points of all discussions are to be confirmed in writing. Distribute this confirmation to the responsible plant personnel; the regional director; and the Branch Chief.**
3. When it is not possible to gain complete cooperation in correcting a definite sanitation problem, the officer-in-charge should contact the regional director. Together, they should arrange for a meeting with top plant management and thoroughly review all previous conversations and actions. During this meeting, plant authorities should be warned that further unsatisfactory reports will require a recommendation for withdrawal of service. **Confirm the warning to the processor in writing, with a copy to the Branch Chief.**
4. When the regional director is unsuccessful in making satisfactory progress, he/she should discuss the situation with the Branch Chief. At the same time, a memorandum should be prepared showing the efforts made to resolve the problem(s). All necessary supporting documents are to be attached. This memorandum should contain a recommendation to the Branch Chief or his/her designated representative for withdrawal of service.

IV. ALTERNATE PROCEDURES FOR MONITORING PLANT SANITATION

A. General

Many processing plants under Processed Products Branch (PPB) in-plant inspection contracts, strive continuously to maintain a clean plant and to produce food under sanitary conditions. Some of these plants assign personnel under the direction of a "sanitation supervisor" or a "plant sanitarian" to carry out the day-to-day activities of cleaning equipment and housekeeping. This designated individual is responsible to management for the plant sanitation program. In these plants, where a complete sanitation program is in place, PPB's value to plant management is greatly improved through the use of more sophisticated sanitation monitoring procedures. Through a combination of selected on-site evaluations and plant record auditing, plant management is continually informed of the effectiveness and reliability of its own sanitation program. In other words, the plant assumes full responsibility for sanitation and performs day-to-day sanitation evaluations according to PPB instructions. The PPB inspector selects key plant areas for thorough examination and reviews plant records against observed conditions and established program criteria.

B. Responsibilities

After official approval of the PPB sanitation program has been granted, the processor's responsibilities are as follows:

1. Assign individual(s) to evaluate sanitation in accordance with PPB instructions;
2. Maintain records of sanitation evaluations and make them available to PPB inspector(s) for verification and review; and
3. Train and supervise all plant personnel whose duties are to keep the plant and its equipment clean and in sanitary condition.

Branch responsibilities, after official approval of the PPB sanitation program, are as follows:

1. Monitor the sanitation program and report any program deficiencies, along with suggestions for improvement, to management; and
2. Provide classroom and workshop types of training for key sanitation program personnel as requested through the area officer-in-charge.

C. Implementation of the Program

A processing plant will not be considered for PPB's alternate sanitation program unless it contracts for year-round inspection and has operated under that contract for at least six (6) months. This prerequisite may be waived with approval from the regional director.

PPB will assess management's ability to effectively control and operate a reliable sanitation program. If the plant has the organization and a history of acceptable sanitation, management should be encouraged to start the verification program.

Official approval will be granted when the following documents are submitted for evaluation:

1. PPB Plant Survey update.
2. Seven (7) consecutive production days of verification for sanitation with no unsatisfactory verification. These verifications must indicate that:
 - a. Each production shift is reliable;
 - b. Plant contact people understand deviations; and
 - c. Can provide proper written response to deviations noted on the inspector's sanitation score sheet.

The officer-in-charge will submit two copies of this material to the regional director for review and approval. One approved copy will be forwarded to the Branch Chief for review and filing.

D. Sanitation Verification Procedures

During the temporary approval period, a processor's sanitation program capability and reliability will have been established. A plant which has gained official approval will then be under a verification procedure which may consist of:

1. Daily on-site verification of entire plant; or

2. Daily on-site verification for specific areas, such as:
 - a. Premises — receiving, dumping, garbage, and waste areas;
 - b. Preparation and processing areas;
 - c. Shop areas, rest rooms, lunchroom, freezer and warehouse facilities;
 - d. Personal hygiene.

AND

3. At a minimum, on-site verifications will be thoroughly conducted in selected plant areas for each shift covered by a PPB inspector.

The combination of methods which the PPB inspector may use will depend on the size and complexity of a plant's operation. After implementing verification procedures and determining the program is still reliable, the level of verification may be reduced.

At plants operating under PPB's Pack Certification Designated Lot Contracts, where the inspector may cover only one production shift, on-site sanitation verifications will be conducted on that shift only. The inspector will, however, audit plant generated sanitation score sheets for the entire production day and cite program deviations.

Exhibit 2 shows a completed example of form FV-416-2, "Sanitation Score Sheet for Frozen Food Processing Plants" to indicate its use as a "USDA Verification." The applicable score sheet for (canned, frozen, citrus, olives, and raisins) is to be used in plants using our services.

CAUTION: PLANT PERSONNEL (PLANT SANITARIAN, ETC.) MAY USE THE APPLICABLE USDA SANITATION SCORE SHEET FOR THEIR EVALUATION, ONLY IF ALL REFERENCE TO USDA AND THE OFFICIAL USDA INSPECTOR ARE DELETED.

Plant management may design their own forms as long as they give equivalent results in a manner easily verified by the PPB inspector.

E. Unsatisfactory Sanitation Program

Verifications performed by the PPB inspector will be classified as either "satisfactory" or "unsatisfactory." The processor's sanitation program will be considered "unsatisfactory" when verifications indicate:

1. A "Minor" and/or "Major" sanitation deficiency is not reported on plant records (incomplete inspection);
2. A "Minor" and/or "Major" sanitation deficiency is inaccurately reported on plant records;
3. A "Minor" and/or "Major" sanitation deficiency is reported on plant records, but the records do not indicate the results of a follow-up inspection;
4. A "Critical" sanitation deficiency.

F. Action on a "Unsatisfactory" Sanitation Program Verification

1. Review of deviation(s) by PPB inspector with plant management and notification to USDA field office;
2. Written report by plant management to PPB inspector within a specified time, indicating the corrective action taken by the plant. The corrective action should include provisions for preventing a reoccurrence of the sanitation program deviation(s) and, if applicable;
3. A "Hold" is placed on all product affected by the critical sanitation deviation(s).

If a plant's quality control has accurately reported their sanitation as "unsatisfactory," action will be as outlined in these instructions.

G. "Unreliable" Sanitation Program

The number of verifications indicating an "unsatisfactory" program will be limited. A processor's program for sanitation under PPB's verification sanitation program will be considered as "unreliable" when:

1. Two verifications performed by PPB inspector are "unsatisfactory" within seven production days; or
2. Three successive days or three days within seven production days of "unsatisfactory" sanitation reports **as reported by the quality control system** within the plant.

H. Procedure During "Unreliable" Period

Applicant will not be permitted to remain on a verification procedure for sanitation. PPB will perform regular sanitation inspection procedures, fully evaluating management's plant sanitation program as covered in this section.

During this period of unreliable status, all PPB and plant records pertaining to sanitation are to be sent to the regional director and the area field office on a daily basis.

On-site inspections and results of the corrective action initiated by plant management will be the determining factors in regaining reliability.

The inspector, with concurrence of the officer-in-charge, will determine when reliability may be re-established.

A memorandum explaining this determination should then be sent to the regional director, with a copy to the National office.

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U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE

"Unsatisfactory 1st Day"

SANITATION SCORE SHEET FOR CANNED FOOD PROCESSING PLANTS

NAME OF PLANT			LOCATION				DATE			D.I.R. NO.		
ABC Processing Company			Processville, TN				09/30/94			183		
RATING SYMBOLS MN - Minor (✓) - Satisfactory MJ - Major CR - Critical U - Unsatisfactory			SIGNATURE OF INSPECTOR(S) W. E. Fields, F. E. Newman, C. F. Gleason									

TIME	1000	1300	1700	2100	0300	0500	TIME	1000	1300	1700	2100	0300	0500
PREMISES							COOK ROOM						
1. Outside areas	MN	✓	✓		✓		1. Exhaust Box	✓		✓		✓	
A 2. Waste disposal	✓		MN	✓	✓		E 2. Syrupers	✓		✓		✓	
3.							3. Seammers	✓		✓		✓	
RECEIVING DEPARTMENT							4. Floors, Gutters and Walls	✓		✓		✓	
1. Boxes	✓		✓		✓		5.						
2. Storage	✓		✓		✓		SYRUP & EVAPORATION DEPARTMENT						
B 3. Dumpsters & Conveyers	✓		✓		✓		1. Tanks and Pipes	✓		✓		✓	
4. Floors, Gutters and Walls	✓		✓		✓		2. Vacuum Pans	✓		✓		✓	
5.							3. Floors, Gutters and Walls	✓		✓		✓	
PREPARATION DEPARTMENT							4.						
1. Washers and Flumes & Pipes	MN		MJ		U		WAREHOUSE						
2. Belts and Elevators							1. General Housekeeping	✓		✓		✓	
3. Graders and Snippers							2. Stacks	✓		✓		✓	
4. Cutters and Slicers De-	✓		✓		✓		G 3. Condiment Room	MN		✓			
C 5. Blanchers, Hoppers	✓		✓		✓		REST ROOMS						
6. Pulpers and Finishers	✓		✓		✓		1. Supplies	✓		✓		✓	
7. Floors, Gutters and Walls	✓		✓		✓		H 2. Wash Basins	✓		✓		✓	
8. De-Waterers Tanks	✓		✓		✓		3. Toilets and Urinals	✓		✓		✓	
9. Chutes	✓		✓		✓		4. Floors and Walls	✓		✓		✓	
10.							5.						
CANNING DEPARTMENT							PERSONNEL						
1. Belts	✓	✓	✓	✓	✓	✓	1. Cleanliness	✓		✓		✓	
2. Fillers and Can Tables	✓	✓	✓	✓	✓	✓	2. Head Covering	✓		✓		MJ	
D 3. Floors, Gutters and Walls	✓	✓	✓	✓	✓	✓	3. Smoking	✓		✓		✓	
4.							4.						
5.							5.						

ITEM NO.	TIME	RATING SYMBOL	SANITATION DEFICIENCIES SHOW RATING, ITEM NO. AND DESCRIBE	TIME LIMIT	TIME CORR.
A1	1000	MN	Ground area below ingredient hoist -- spilled spices, etc. on floor (told Bennett)	24 hrs.	1300
B	1000		Receiving department is much improved since new clean-up man was hired.		

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C 1	100 0	MN	Product residue on underside of long wire grate on whole peel line -	1700	(see
			between shift clean-up not effective -- will need attention prior to next shift.		1700)

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE

SANITATION SCORE SHEET FOR PROCESSING PLANTS (*Continuation Sheet*)

NAME OF PLANT A B C Processing Company	LOCATION Processville, TN	DATE 09/30/94	D.I.R. NO. 183
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RATING SYMBOLS

(✓) - Satisfactory

MN - Minor

MJ - Major

CR - Critical

U - Unsatisfactory

SIGNATURE OF INSPECTOR(S)

ITEM NO.	TIME	RATING SYMBOL	SANITATION DEFICIENCIES SHOW RATING, ITEM NO. AND DESCRIBE	TIME LIMIT	TIME CORR.
G 3	100 0	MN	Condiment room -- spilled spices, etc.	24 hrs.	1700
A 2	170 0	MN	Offensive odor around cull hopper (told Stevens)		2100
C 1	170 0	MJ	Slime on underside of long wire grate on whole peel	0030	
			line (told Stevens) see C 1 @1000		
C 1	003 0	U	Same condition as 1700 (Byron said, They are going		
			down for general clean-up at 0700)		
H	----		Dockside men's room looks good since painting.		
I 2	003 0	MJ	Two graders on line 6 without hairnets (told Byron)		immed.
			overall sanitation rating		
			UNSATISFACTORY		

			<i>account inadequate follow-up on</i>		
			<i>Major deficiency (see C 1)</i>		
			<i>Bill Fields</i>		
			<i>Inspector-in-Charge</i>		

FV FORM 416-5 (1-82) (Edition of 5-81 is obsolete)

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE

USDA Verification**"Unsatisfactory" 1st Day****SANITATION SCORE SHEET FOR FROZEN FOOD PROCESSING PLANTS**

NAME OF PLANT	LOCATION	DATE	D.I.R. NO.
NANCY'S FRUITS	PRODUCE TOWN, USA	10/28/94	178

RATING SYMBOLS	SIGNATURE OF INSPECTOR
MN - Minor CR - Critical (✓) - Satisfactory MJ - Major U - Unsatisfactory	N. SANDERS, J. L. TIPKINS, J. TUCKER

TIME	0700	1800	0100	TIME	1000	1800	0100
PREMISES				SYRUP ROOM			
1. Outside Areas		✓		1. Outside and Walls			
A 2. Waste Disposal		✓		E 2. Tanks and Pipes			
3.				3. Sugar and Salt Storage			
RECEIVING DEPARTMENT				4.			
1. Boxes and Tote Bins		✓		FREEZER FACILITIES			
2. Storage		✓		1. General Housekeeping			✓
3. Dumpers and Conveyors		MN		F 2. Tunnels, Belts and Plates			✓
B 4. Floors, Gutters and Walls		✓		3. Stacks, Bins, and Floors			✓
5.				4.			
PREPARATION DEPARTMENT				REST ROOMS			
1. Washers and Flumes, <i>Lima Beans</i>	✓		✓	1. Supplies		MJ	
2. Belts and Elevators	MJ		✓	G 2. Wash Basins		✓	
3. Snippers and Graders	✓		✓	3. Toilets and Urinals		✓	
4. Cutters, Slicers and Corers	✓		✓	4. Floors and Walls		✓	
C 5. Blanchers	MJ		MN	5.			
6. Hoppers and De-waterers	✓		✓	PERSONNEL			
7. Floors, Gutters and Walls	✓		✓	1. Cleanliness	✓		
8. <i>Chiller</i>	MN		✓	H 2. Head Covering	✓		
9.				3. Smoking	✓		
10.				4.			
PACKING DEPARTMENT							
1. Belts and fillers			✓				
2. Closers and Wrapping Machine			✓				
D 3. Floors, Gutters and Walls			MN				
4.							
5.							

ITEM NO.	TIME	RATING SYMBOL	SANITATION DEFICIENCIES SHOW RATING, ITEM NO. AND DESCRIBE	TIME LIMIT	TIME CORR.
			Verification of selected areas and audit of plant sanitation		
			reliable program.		
			Plant rating at 1300 -- "UNSATISFACTORY" --Major deficiencies C2	1200	1400
			corrected in specified time.		
			Production has been told to do a more thorough cleaning during noon break.		
			Pete Johnson. Q. C. Manager		

SECTION 2

EXAMPLES OF SANITATION DEFICIENCIES

I. PROCESSED F&V PLANTS

- A. Premises-Waste or Garbage Areas-Receiving Areas-Dumping Areas
1. Minor Conditions
 - a. Overflow or spillage that adversely affects operations
 - b. Accumulation of freshly spilled product
 - c. Dusty roads, or muddy areas
 - d. Insect "concentration" and/or harborage
 - e. Waste not removed timely
 - f. Litter, or paper and trash
 - g. Dirty raw product containers
 - h. Overflow, or backup of waste disposal
 - i. Old, decaying, or moldy products not properly handled
 - j. Offensive, odorous conditions
 - k. Evidence of rodents and/or harborage conditions (grass, weeds, old equipment, junk, and other similar materials)
 - l. Slime on equipment, floors, or paving
- B. Preparation and Processing Areas
1. Minor Conditions
 - a. Overflow, or excessive water on floors
 - b. Product on floor after cleaning
 - c. A few insects in area
 - d. Fresh product, or product residue, on equipment after cleaning
 - e. Dirty walls, windows, ledges
 - f. Excessive product on floors during operations
 2. Major Conditions
 - a. Dirty, decaying, or discolored product on parts of equipment that may contaminate the product
 - b. Slime on equipment
 - c. Insects in areas near vulnerable product
 - d. Loose rust, flaking paint, dust, cobwebs, or mold on overhead areas, or dirt on part of equipment that may come in contact with or contaminate the product after it is vulnerable. This includes overhead areas, underside of drip pans, motor mounts, walkways, and crossovers
 - e. Offensive, odorous condition
 - f. Product containers that are rusty, dirty, or that contain cleanup water or sediment
 - g. Product holding containers (bins, tubs, pans) nested after having been in contact with unsanitary situations
 - h. Container cleaners not operating properly
 - i. Misuse of empty product containers such as drinking cups, waste receptacles
 3. Critical Conditions During Operations
 - a. Vulnerable product that has been in contact with an unsanitary condition (such as floors) returned to line or packaged for use
 - b. Dirty containers or equipment brought in contact with product
 - c. Insects in or on product or product contact surfaces
 - d. Condensate from dirty surfaces dripping on product
 - e. Filled, open containers stacked in such a manner as to contaminate the product
 - f. Dirty ice in product
 - g. Maintenance or repair work done in such a manner as to contaminate the product
 - h. Sediment or foreign material in packing media, fillers, or holding tanks
- C. Warehouse and Shop Areas
1. Minor Conditions
 - a. Litter, trash, cigarette butts, and other materials on floor
 - b. Untidy, dirty, or wet storage conditions for containers, other materials and supplies
 2. Major Conditions

Overall storage conditions that are attracting insects, birds, rodents, and/or animals which may contaminate the product
- D. Rest Rooms
1. Minor Conditions
 - a. Room not clean; presents a poor general appearance
 - b. Toilets and sinks not properly cleaned
 - c. Excessive water on floor
 2. Major Conditions
 - a. Absence of toilet tissue, suitable hand-cleaning soap or detergents, paper towels, and any other essential supplies
 - b. Toilet and sinks very dirty and not functional
 - c. No hot water readily available for washing hands
- E. Personal Hygiene 1/
1. Minor Conditions
 - a. Wearing unsecured jewelry
 - b. Chewing gum or eating except in authorized areas
 - c. Wearing improper clothes for work, such as sleeveless shirts

- d. Personal items on unused equipment

1/ *This part of the plant sanitation program, particularly, should be controlled by management. It will be monitored occasionally by USDA. To have an effective program in this area, management must provide adequate training on good personal hygiene practices. These rules are to be conspicuously posted throughout the plant.*

2. Major Conditions

- a. Smoking or spitting in plant processing area
- b. Uncovered, or improperly covered hair (hat, hairnet, or beard cover)
- c. Wearing very dirty clothes
- d. Starting or returning to work without washing or sanitizing hands and/or gloves
- e. Using unhygienic practices

3. Critical Conditions

- a. Employees on the production line having uncovered infections or cuts
- b. Direct contamination of product by sneezing or coughing

F. Lunchroom Area

1. Minor Conditions

- a. Untidy areas and facilities
- b. Few flies

G. Freezer Facilities

1. Minor Conditions

- a. Buildup of frozen spilled product from broken packages

2. Major and/or Critical Conditions

- a. Grease, oil, or dirt contamination of product on belts in freezing tunnels

SECTION 3**PLANT SURVEY****I. PLANT SURVEY**

The plant sanitation survey form consists of the following:

- A. Plant organization, management, and program information;
- B. Plant facilities, equipment, and environmental factors;
- C. Plant operational conditions; and
- D. Survey evaluation and review.

The primary purpose of a survey is to determine whether a plant is adequate and acceptable for inspection service on a contract basis. A plant survey is to be made for all new applicants who wish to sign a contract for services, as well as those who have had contracts on a continuing basis. New applicants are considered to be those processors who have never had a contract service agreement, or those without a contract for the previous processing season.

Prior to the inauguration of any inspection service, plant survey items A., B., and D., shown above must be completed. Item C. (the operational portion of the survey) may also be evaluated at this time if the plant is operating. When survey requirements are found to be acceptable, the applicable contract service form shall be completed and distributed immediately according to Branch instructions. When it is not possible to evaluate the operational part of the survey before granting service, the survey form will be held until this can be done. Distribution of the application and contract of agreement for inspection/grading service is not delayed pending completion of the survey.

Attach a forwarding memo to the contract form stating that the plant is approved for service and that operational conditions will be evaluated within ten days after processing begins. A copy of the completed survey is promptly distributed to the appropriate regional office.

For other than new applicants, plants should be surveyed at least once a year. This applies to both seasonal and year-round plant contracts. The plant survey shall be completed by the officer-in-charge, his/her assistant, or an area supervisor. For certain short-term, in-plant assignments an experienced inspector may assist the supervisor by completing a "preliminary survey." The supervisor must approve all preliminary surveys. It is imperative that all final surveys be made by the supervisor as soon as practical after a plant begins processing. Normally, it is expected this will be accomplished within a period of ten days. The plant survey shall be distributed as follows:

1. Original to plant management;
2. Copy to plant inspector's file;
3. Copy maintained at the area field office;
4. Copy to regional office; and
5. Copy to National office.

When a plant is being considered for continuous inspection approval, the survey procedures outlined in 175-B-75 for handling this type of agreement are to be followed. The actual survey is performed and distributed in the same way as with other types of contracts and agreements.

All plant survey reports and attachments shall be legible. Each section shall be completed in detail. Recommendations are to be definite and understandable. Be sure to complete all portions of the important evaluation and review section. Documents are to be dated and signed in the appropriate places.

On the front page of all plant surveys and related attachments, indicate the type of contract or service involved, i.e., Continuous, Pack Certification, Letter Agreement, request from applicants for potential School Lunch, Needy Family, or Operational Rations contract. Also indicate the product being processed at the time of the survey. Based on the results of the survey the plant should be *evaluated* as either acceptable or unacceptable. At the bottom of the front page indicate if the plant is approved, not approved, or conditionally approved. If corrections are mandatory in order to approve the plant, conditional approval is appropriate. The plant is unacceptable if conditions are present which would result in product contamination, or the plant is unwilling or unable to meet the essential requirements.

Deficiencies are rated as minor, major, or critical. Each deficiency will be described and the date the plant intends to correct the deficiency noted.

Survey results are to be discussed with responsible plant management. The inspector on duty should be present. There should be complete understanding regarding the correction of all deficiencies.

II. ESSENTIAL REQUIREMENTS OF THE SURVEY

Many of the questions and statements on the plant survey are points of information and/or recommendation. They become a requirement only when an incident becomes serious enough to cause an unsanitary condition.

There are, however, certain essential requirements included in the plant survey. Unless these requirements are satisfied the plant will not be approved, and the Branch will not enter into a contract for in-plant inspection. The requirements are as follows:

- A. Parking lots and drives are to be surfaced or treated to control dust and dirt;
- B. All exterior openings of the preparation and packaging rooms are to be enclosed or screened (metal or effective air screens) to protect finished product from birds, insects, rodents, and other vermin;
- C. Screened, vented toilet facilities are to be designed so they do not open directly into rooms where products are handled;
- D. Can cleaners (steam, air, or water) are to be on each line for glass, tin and semirigid containers;
- E. Non-wood, non-corrosive material is to be used on all product contact surfaces where the product is exposed. This means when the product has been pitted, peeled, cut, or during and after blanching, or is in such a form as to be subject to contamination. Special attention must be given to surfaces of corrosive material to keep them clean, free of rust or flaking paint and other foreign material in order to avoid product contamination;
- F. Lights above all product lines are to be shielded or shatterproof;
- G. Floors and gutters are to be constructed to drain well and be free of pitting or cracks which prevent proper cleaning. Wide and deep cracks and extremely rough sections which are difficult to clean must be repaired or replaced;
- H. Adequate time and proper equipment is provided for the cleanup program to be effective during shifts and between shifts so as to sanitize, rather than rinse, processing lines;
- I. Manufacturing practices that prevent product contamination shall be followed. This includes, but is not limited to, keeping overhead areas free from flaking paint, dust, condensate, and dirt; and
- J. There is frequent and timely removal of waste material.

III. FOLLOW-UP OF SURVEY

If conditional approval was granted, changes required will be listed on the final page of the survey. Deficiencies, such as in manufacturing practices, are to be corrected immediately and so indicated in the date corrected column. Other deficiencies should be corrected in accordance with agreed timetables.

After agreement with the processor is reached on realistic and reasonable timetables for corrections of deficiencies, the area officer-in-charge will confirm these dates in writing. This confirmation will list each deficiency along with the correction dateline. Copies of this letter shall be sent to the regional director and the Branch Chief. If deficiencies are not corrected within the specified time, the area supervisor will write a letter to the processor. The letter will state what action will be taken if the deficiencies are not corrected.

As corrective action is taken on each deficiency, the correction date is shown in the appropriate column of the follow-up summary sheet for deficiencies. The area supervisor, assisted by the plant inspector, are responsible for keeping this current in accordance with the agreed correction datelines. Distribution of the follow-up summary sheet for deficiencies is the same as the plant survey.

It is well to remember that improvements made by the plant during the year are recognized. Recognition of improvements in sanitation conditions are important.

Many desired corrections and improvements in the processor's sanitation program may be acquired by being alert to what the processor is doing. One method of communicating is to meet with the processor prior to the packing season and again shortly after the season is over.

A. Pre-Season Meeting

The points to be considered at a pre-season meeting with the processor are as follows:

1. Review in detail any problems resulting from the sanitation program during the previous season. Problem situations are considered to be those which have persisted throughout the season;
2. Establish effective lines of communication and make sure a competent plant employee is assigned the responsibility for sanitation;
3. Review our sanitation policies and procedures. Define USDA and plant management sanitation responsibilities. There should be a complete understanding of our requirements and inspection coverage;
4. Determine if all necessary corrections of deficiencies in plant facilities and equipment have been made by the agreed date(s). Ascertain if the plant is ready to begin operation; and
5. Solicit comments and suggestions from plant management regarding improvements in the program.

B. Post-Season Meeting

The points to be considered at a post-season meeting with the processor are as follows:

1. Review the effectiveness of the overall sanitation program during the past season;
2. Discuss in detail all sanitation problem situations of the past year. Use the sanitation score sheets as a basis for this discussion;
3. Make a list of the plant facilities and equipment items which will need to be improved or corrected. A reasonable and practical corrective action date should be agreed upon. Most of the corrections can be made during the "off-season"; and
4. Strive to create and maintain a good working relationship with plant management in their efforts to achieve high standards of sanitation.

IV. SUPPLEMENTARY GUIDELINES IN THE CORRECTION OF PLANT SURVEY DEFICIENCIES

Processors using our services have made many improvements of plant facilities and processing procedures. Discussions with plant management representatives have resulted in working out agreeable time frames to correct plant survey deficiencies.

Current research projects involve the development of new equipment and processing procedures which will necessitate many changes in plant operations. In view of future innovations and the economic impact they will have on the food processing industry the Branch sanitation program and policy will be as follows:

- A. To continue to encourage essential sanitation requirements;
- B. To seek positive alternatives to problem areas; and
- C. Advocate a continuing cooperative effort and working relationship with the industry.

SECTION 4**FOOD AND DRUG ADMINISTRATION****I. REGULATORY VISITS****A. Purpose**

Food and Drug Administration (FDA) inspectors visit processing plants for various reasons in connection with their overall regulatory responsibilities. Ordinarily, the purpose of these visits are as follows:

1. To perform a sanitation inspection, including the condition of raw materials;
2. A routine sample collection, e.g., pesticide analyses; or
3. A processing compliance procedure for low acid products.

As a general rule, our primary interest is in the sanitation inspection aspects of the FDA review.

II. ACTION BY INSPECTORS**A. Agreement with Federal Food and Drug Administration**

The agreement between the Agricultural Marketing Service (AMS) and the FDA (Appendix B) outlines the authority or basis for cooperative efforts between these two agencies.

Inspectors should carefully study the agreement and the comments which outline the reasons and interpretations.

Although this instruction deals directly with FDA relationships under the agreement, the same basic philosophy applies to state, county, and other regulatory agencies. However, since we have no agreement with them, they are not obligated to cooperate with us. We would, of course, cooperate with such agencies whenever possible.

B. Plant Visits

When an FDA inspector visits a plant to which a PPB inspector is assigned, he/she is under instruction to invite the PPB inspector to accompany him/her on a tour of the plant. Since the FDA inspector must always contact plant management when they enter the plant and announce the intended purpose of his/her visit, the plant is fully aware of their presence and can accompany both FDA and PPB on the tour.

If the PPB inspector is not contacted in the early stages of the visit, they should introduce themselves to the FDA inspector and tactfully ask to be present during the tour.

When the FDA visit extends over a considerable length of time, the PPB inspector should not devote any more time on the tour than he/she can spare. The PPB inspector should ask to be advised at the conclusion of the visit so that the FDA report can be reviewed.

The FDA inspector's purpose is to gather information concerning the condition of the raw and finished product and observe packing practices and facilities. During the inspection tour the FDA inspector may or may not comment on conditions that might substantiate seizures at some later date. The FDA inspector would not normally make any statement that would give unqualified approval or disapproval.

Poor or insanitary conditions or practices, if encountered, are later associated with analyses of samples drawn at the time of inspection or from trade channels before any seizure action is taken.

PPB inspectors are **not** to argue with FDA inspectors or become involved in discussion between them and plant management except to make pertinent statements of fact, when requested. Any argument or difference of opinion between representatives of two government agencies does not lend respect to either agency or government employees in general.

PPB inspectors will not turn over any records to FDA. These records are given to the plant which may in turn permit FDA to see them.

1. PPB Responsibilities

An outline of the PPB inspector's responsibilities are as follows:

- a. The PPB inspector will be invited by FDA inspectors to accompany him/her on their tour;
- b. The PPB inspector will accompany the FDA inspector on at least part of the tour;
- c. The PPB inspector shall not argue with FDA inspector about the plant's sanitary condition. Comment only on the facts of any particular sanitation deficiency;
- d. The PPB inspector shall not disclose or turn over any records to the FDA inspector. This is the responsibility of the plant (see File Code 170-A-1); and
- e. The PPB inspector shall document the FDA inspector's visit on form FV-425. Exhibit 3 contains a facsimile of form FV-425, "Report of Regulatory Agency Inspection." This form is to be used to document visits by all regulatory agencies, such as OSHA, EPA, state, county, or city health agencies.

If any discrepancies exist between the PPB inspector and the Regulatory inspector, they should be fully explained. The "Remarks" section should contain enough detail so that supervisory personnel can accurately evaluate the conditions.

Complete Form FV-425 in quadruplicate. Retain one copy with the daily inspection report or the sanitation score sheet. Send the original with a copy of the sanitation score sheet and Food and Drug Form 483 to the Branch Chief. Distribution is also made to the area field office and the regional office.

EXHIBIT 3**File Code 159-A-1
July 1995**

U.S. DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING SERVICE FRUIT AND VEGETABLE DIVISION REPORT OF REGULATORY AGENCY INSPECTION	NAME OF PLANT	DIR. NO.
	LOCATION OF PLANT (City and State)	
	PLANT TOUR BY REGULATORY INSPECTOR(S)	
	BEGINNING DATE AND HOUR	ENDING DATE AND HOUR

INSTRUCTIONS: Complete in triplicate. Retain copy. Send original to Washington and copy to Regional office.
 Attach copy of sanitation scoresheet(s) and copy of regulatory agency report.

NAME(S) OF REGULATORY INSPECTOR(S)	AGENCY REPRESENTED		
	FEDERAL FOOD AND DRUG	STATE FOOD AND DRUG	OTHER (Specify)

PRODUCTS BEING PROCESSED

	YES	NO
Did USDA inspector accompany regulatory inspector(s) on tour? (If "No," explain under "Remarks.")		
Were the comments (oral or written) of the regulatory inspector(s) in substantial agreement with USDA reports or opinions? (If "No," indicate discrepancies under "Remarks.")		
Did plant management make required or recommended corrections? (Give details under "Remarks.")		

REMARKS

DATE OF REPORT	INSPECTOR IN CHARGE (Signature)
----------------	---------------------------------

III. ACTION BY SUPERVISORS

If substantial disagreements are reported between the FDA inspector and the PPB inspector in evaluating conditions of the plant, raw materials, or other pertinent factors and our supervisor is unable to resolve these differences, or there are numerous deficiencies, a report shall be made at once to the regional director and the National office as to what further action to take. The officer-in-charge will report to the local FDA office as required in the Memorandum of Understanding, paragraph 5, under "The Agricultural Marketing Service will:"

IV. ACTION BY NATIONAL OFFICE

All actions under the agreement other than which is specified above will be handled by the National office. This includes supplying information relative to specific lots of product being considered for regulatory action by FDA.

V. INSPECTION OF PRODUCTS UNDER SEIZURE BY A REGULATORY AGENCY (FILE CODE 130-A-60)

Refer to File Code 130-A-60, "Inspection of Products Under Seizure by Regulatory Agencies" for Branch policy regarding products under seizure or quarantine by regulatory agencies on Federal, State, County, or City levels, or in an instance in which it may not be to the best interest of the government to perform such inspection.

APPENDIX B

**MEMORANDUM OF AGREEMENT BETWEEN THE AGRICULTURAL
MARKETING SERVICE AND THE FOOD AND DRUG
ADMINISTRATION CONCERNING THE INSPECTION AND
GRADING OF FOOD PRODUCTS 1/**

The Food and Drug Administration (FDA) of the Department of Health, Education and Welfare is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act. In fulfilling its responsibilities under the Act, FDA's activities are directed toward the protection of the public health of the nation by insuring that foods are safe and wholesome and products are honestly and informatively labeled. This is accomplished by inspecting the processing and distribution of foods and examining samples thereof to assure compliance with the Act. FDA also promulgates under the Act mandatory standards of identity, quality, and fill of container for food products after appropriate notices and hearings.

The Agricultural Marketing Service (AMS) of the U. S. Department of Agriculture, under the authority of the Agricultural Marketing Act of 1946, carries out certain voluntary service functions designed to aid in the efficient marketing of agricultural products. These include the development of commercial grade standards and specifications for foods, and furnishing inspection and grading services, including the issuance of certificates of quality and/or condition, to producers, processors, shippers, buyers, or other interested parties. The major purpose is to assist producers in preparing better quality of wholesome products and to provide objective information by means of official certification concerning the grade, quality, or condition of a product which will be of maximum assistance to all interested parties engaged in marketing functions.

The two agencies have certain related objectives in carrying out their respective regulatory and service activities. Therefore, it is believed desirable from the standpoint of public interest to set forth in this Memorandum of Agreement the working arrangements which are being followed or adopted in the interest of each agency discharging as effectively as possible its responsibilities related to inspection and standardization activities for food products.

1/ This Agreement does not apply to egg products, inspection of which is covered by the Egg Products Inspection Act, nor to grains, including rice, dry beans, peas, or lentils, which will be covered by a separate memorandum of agreement between AMS and FDA.

The Agricultural Marketing Service will:

1. Supply to FDA headquarters a complete list of all food processing and packing plants which are operating under AMS continuous or other resident-type inspection or grading contracts. This list will set forth the type of service provided and the food products involved. AMS will immediately advise the appropriate FDA field office of those plants subject to withdrawal or suspension of service, termination of contract or denial of inspections because of sanitation or other current good manufacturing practice deficiencies;
2. Investigate any report from FDA to the effect that a processor or packer operating under contract with AMS has not corrected objectionable conditions found to exist by FDA, and will take action in accordance with AMS regulations and contracts;
3. Decline to inspect or grade samples of products which have been seized by FDA, or which are known to be involved in formal FDA actions. This does not preclude reinspection of legally authorized

samples by AMS if the FDA seizure or other actions involved products which had previously been inspected or graded by AMS;

4. Decline to assign a U. S. grade or permit the use of government official marks or other approved identification on a food product which is considered adulterated under the Federal Food, Drug, and Cosmetic Act, of such type and/or in such amounts so as to result in the food product being subject to regulatory action by FDA or is otherwise found to be not suitable for grade assignment. AMS will make such examinations and tests as are reasonably feasible for those materials and substances that would be likely to contaminate the product;
5. Report to the appropriate FDA field office information on any lot of produce which, upon inspection, AMS declines to assign a grade unless such produce is so reconditioned as to comply with FDA requirements and/or qualify for grade assignment, or is segregated and disposed of for non-food use or otherwise lawfully shipped or sold;
6. Furnish FDA headquarters, on request, with any pertinent information concerning the grade or quality determination relative to specific lots of products inspected or graded by AMS that have been proceeded against or are being considered for action by FDA;
7. Report on the inspection certificate any pertinent codes or other marks that will serve to identify the specific goods which are inspected or graded;
8. Inform FDA headquarters whenever it has information that an employee or USDA-licensed inspector is to be, or has been, subpoenaed as a witness at judicial proceedings involving FDA action and advise FDA of the nature of his proposed testimony.

The Food and Drug Administration will:

1. Recognize that the AMS service provided in connection with the voluntary contract inspection of fruit and vegetable processing establishments contributes to protection of consumers and aids FDA in enforcement of pertinent statutes. The AMS inspection service will not diminish FDA authority to inspect but should minimize FDA inspections in establishments under AMS contract inspection. In this regard, AMS inspectors will routinely advise contract establishments of pertinent FDA requirements, advise them on how to comply, and provide advice on compliance. AMS inspectors may not act as FDA inspectors but their inspections and consultations with FDA should reduce the necessity for FDA inspections;
2. Invite the AMS inspector stationed at a plant which is operating under AMS inspection to accompany the FDA inspector during his inspection of such plant. The FDA inspector will point out or discuss with the AMS inspector any conditions noted which may result in violations of the Federal Food, Drug, and Cosmetic Act;
3. Request AMS headquarters for any pertinent information concerning the grade or quality determinations relative to specific lots of products that have been proceeded against or are being considered for action by FDA and are known or believed to have been inspected by AMS. FDA will take into consideration the results of AMS inspection certificates and other available data unless it has evidence that the product does not meet legal requirements as a food or has deteriorated to such an extent, subsequent to AMS inspection, as to make it unacceptable as food;
4. Immediately notify the appropriate AMS field office concerning the details of objectionable conditions whenever such conditions are found to exist in processing or packing plants where AMS is currently

conducting inspection of products, or in other food plants, when FDA believes such information would be of value to AMS in its inspection and grading activities;

5. Whenever possible, mark the claimant's samples of seized products in such a manner that AMS inspectors or graders will recognize such post-seizure samples;
6. Discuss with AMS headquarters the criteria used by FDA in order to provide the maximum assurance that AMS does not classify a food as acceptable which FDA would consider actionable under the Federal Food, Drug, and Cosmetic Act;
7. On request of AMS review labels, legends, stamps, and other official marks for products packed under the various inspection services of AMS from the standpoint of possible conflict with the misbranding provisions of the Federal Food, Drug, and Cosmetic Act.

It is mutually agreed that:

1. Both agencies will maintain close working relations with each other, both in headquarters as well as in the field;
2. Proposed regulations by either agency establishing or amending any food products standard will be referred to the other agency for review and comment prior to issuance;
3. Both agencies will cooperate jointly and with industry in the improvement of sanitation and food handling practices in processing plants. Both agencies will mutually exchange data and cooperate in the development of sampling plans, methodology, and guidelines for determining natural and unavoidable defects common to products inspected and graded by AMS;
4. Both agencies will work with industry toward greater efficiency in connection with improvement in coding methods;
5. Both agencies will cooperate in the handling of those cases of misbranding which also come under the provisions of the Perishable Agricultural Commodities Act of 1930, as amended;
6. Each agency will designate to the other a central contact point to which communications dealing with this Agreement, or matters affected thereby, may be first referred for attention;
7. Nothing in this Agreement modifies other existing agreements, nor does it preclude entering into separate agreements setting forth procedures for special programs which can be handled more efficiently and expeditiously by such special agreement;
8. The provisions of this memorandum may be modified at any time by mutual agreement.

FOR THE AGRICULTURAL MARKETING SERVICE

Date

ApprovedAdministrator
Agricultural Marketing Service

FOR THE FOOD AND DRUG ADMINISTRATION

Date

ApprovedCommissioner
Food and Drug Administration

Effective Date. This agreement becomes effective _____ (date of publication in the
FEDERAL REGISTER) and supersedes Memorandum of Understanding dated August
28, 1973

SECTION 5**SANITATION REQUIREMENTS****I. GENERAL**

Although the Branch refers specifically to the Food and Drug Administration regulations as our sanitary requirements, this does not excuse plant management from complying with any state, local, or contract requirements that apply.

Regulations applying to plant sanitation requirements are issued under section 402 (a) (4) and 701 (a) of the Federal Food, Drug, and Cosmetic Act and now appear in Title 21, Part 110 of the Code of Federal Regulations published by the Food and Drug Administration, Department of Health and Human Services.

A reprint of the Food and Drug Administration regulations covering Title 21, Part 110 can be found in File Code 159-A-2.

APPENDIX A

United States Department of Agriculture
Agricultural Marketing Service
Fruit and Vegetable Division
Processed Products Branch

PLANT SURVEY

PLANT FACILITIES, EQUIPMENT, ENVIRONMENT, MANAGEMENT AND OPERATIONS

NAME OF PLANT

LOCATION OF PLANT

AREA FIELD OFFICE

TYPE OF CONTRACT OR SERVICE

PRODUCT(S) PACKED DURING SURVEY

ANNUAL SURVEY (FINAL) COMPLETED BY

DATE

OVERALL SANITATION LEVEL

ACCEPTABLE

UNACCEPTABLE

RECOMMENDED APPROVAL

YES

NO

CONDITIONAL

NAME OF COMPANY	
LOCATION OF MAIN OFFICE (Complete mailing address, including Zip Code)	LOCATION OF PLANT COVERED BY THIS REPORT (Complete mailing address including Zip Code)
STATUS OF PROPRIETORSHIP <div style="display: flex; justify-content: space-between;"> INDIVIDUALLY OWNED PARTNERSHIP </div> <div style="display: flex; justify-content: space-between;"> CORPORATION COOPERATIVE </div>	OTHER (Specify)
OWNERS OR OFFICERS	
NAME <hr/> <hr/> <hr/>	TITLE <hr/> <hr/> <hr/>
MANAGERS, SUPERINTENDENT, OR RESPONSIBLE FOREMAN	
NAME <hr/> <hr/> <hr/>	TITLE <hr/> <hr/> <hr/>
AUTHORIZED PERSON RESPONSIBLE FOR SANITATION	
NAME <hr/>	TITLE <hr/>
TO WHOM DO THEY REPORT? <hr/>	
PERSON WITH WHOM THE USDA INSPECTOR IS TO DEAL	
NAME <hr/>	TITLE <hr/>

CODING SYSTEM - CODE MARKING SYSTEM INCORPORATES

COMMODITY	TYPE	GRADE	OTHER (SPECIFY)
DATE	STYLE	SYRUP	
SHIFT	SIZE	PLANT	
		PERIOD	

INSPECTION SERVICE

WHAT IS THE REASON FOR THIS COMPANY APPLYING FOR INSPECTION SERVICE?

DOES THIS COMPANY INTEND TO USE SHIELDED LABELS OR OTHER APPROVED IDENTIFICATION OF CONTAINERS?

NONE

LIMITED

EXTENSIVELY

FILL IN THE FOLLOWING INFORMATION REGARDING PRODUCTS PACKED BY THIS PLANT

COMMODITY	SEASON	COMMODITY	SEASON

**DEFICIENCIES
DEFINITION OF TERMS
RATING**

MINOR (MN) - Do not result in product contamination but are not desirable.

MAJOR (MJ) - May result in product contamination or are highly objectionable.

CRITICAL (CR) - Result in product contamination.

OVERALL SANITATION LEVEL

ACCEPTABLE - No critical or major defects that would have a significant impact on product contamination.

UNACCEPTABLE - Plant practices or operations present that result in product contamination or potential product contamination.

A. SANITATION CONTROLS

	YES	NO	Rating
1. Is there a planned sanitation program that includes an educational training program for personnel hygiene and plant sanitation?			
2. Does the plant have an authorized person charged with the responsibility to administer an effective sanitation program?			
3. Does the plant maintain or utilize a bacteriological laboratory?			
4. Does the plant maintain or utilize a pesticide residue laboratory?			
5. Is there an adequate program to prevent rodents, birds or animals on the premises, in the receiving area, and/or warehouse? *			
6. Is there an adequate program to control insects on the premises, in the receiving area, processing area, and/or warehouse? *			
7. Does the plant contract for a commercial exterminator?			

DEFICIENCIES

ITEM Letter And Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

B. PREMISES

Parking Lot and Yard Surfaces: Paved Blacktop Dirt Gravel

	YES	NO	Rating
1. Are there significant deficiencies in the general appearance of the premises?			
2. Are weeds, trash, rubbish, unused machinery or "junk" a problem?			
3. Are there conditions on adjacent properties that could cause sanitation problems?			
4. Is there evidence of rodent/insect harborage?			
5. Are there offensive odors? *			
6. Is there a dust or soot problem? *			
7. Is there a drainage problem? *			

DEFICIENCIES

ITEM Letter And Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

C. RECEIVING AREA

	YES	NO	Rating
1. Is the general appearance satisfactory?			
2. Is the area designed to facilitate cleanup?			
3. Does there appear to be adequate cleanup equipment available?			
4. Is the area free from offensive odors? *			
5. Is debris and product refuse removed on a timely basis? *			
6. Are there sufficient facilities for handling raw materials in an efficient and expeditious manner? *			
7. Do raw material storage and handling practices preclude contamination by environmental hazards such as rodents, birds and insects? *			
8. Are raw product containers cleaned and stored satisfactorily? *			
9. Are holding tanks, holding bins, conveying equipment and devices adequately cleaned? *			

DEFICIENCIES

ITEM Letter And Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

D. PLANT CONSTRUCTION AND DESIGN

	YES	NO	Rating
1. Is the general appearance, construction and condition of the buildings satisfactory?			
2. Are all exterior openings (including doors, windows, and wall openings) equipped with screens in good condition or otherwise protected?			
3. Are exterior screen doors self-closing and/or air screens operating satisfactorily?			
4. Are floors constructed of materials which can be well cleaned?			
5. Are walls and ceilings in good condition and of the type that can be kept clean?			
6. Are lights shatterproof or equipped with protective shields?			
7. Is there an in-line chlorination or other sanitizing system?			
8. Are there sufficient facilities including steam and water outlets throughout the plant for cleanup?			
9. Is there a rodent-proof storage area for salt, sugar, and other product ingredients?			
10. Is there proper locked storage for chemicals, cleaning compounds, and similar materials separate from product ingredients and container storage?			
11. Is there sufficient lighting to permit efficient operations and cleaning? *			
12. Do floors, gutters or drains have sufficient slope and outlets to drain adequately? *			
13. Are buildings adequately ventilated so that all areas are kept reasonably free from excessive heat, steam, condensation, vapors, smoke, or fumes? *			
14. Are there leaks in the roof? *			
15. Are there leaking pipes or valves? *			
16. Is the tool shop neat, orderly and well maintained? *			

DEFICIENCIES

ITEM Letter And Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

E. PROCESSING AREA, EQUIPMENT AND FACILITIES

	YES	NO	Rating
1. Is the general appearance satisfactory?			
2. Are the equipment and area structures free from flaking paint and rust?			
3. Are all product contact surfaces of equipment, containers and utensils made of non-absorbent corrosion resistant material that will not affect the product by chemical or physical contact?			
4. Is the equipment constructed and located so that product contact surfaces are accessible for cleaning, maintenance and inspection?			
5. Are equipment, containers, and utensils in good condition?			
6. Is idle or unused processing equipment clean and located or arranged so as not to interfere with cleanup?			
7. Are equipment, containers and utensils constructed of wood? <i>(If so, for what purpose and what is the condition. Show in Remarks.)</i>			
8. Are product contact brushes in good condition?			
9. Are motors, conveyor belts and drive mechanisms located and protected so that oil or grease will not contaminate the product?			
10. Are cross belts adequately protected?			
11. Are catwalks and stiles properly constructed and located to prevent product contamination?			
12. Is the area free from offensive odors? *			
13. Are containers and utensils used in handling the product cleaned, stored, and utilized in such a manner as to preclude an insanitary condition? *			
14. Are can cleaners (steam, air, or water) on each line for glass, tin, and semirigid containers?			
15. Is the can cleaning system adequate for cleaning containers?			
16. Are product belts clean and in good condition? *			
17. Are gutters and drains in good repair, functioning satisfactorily, and properly fitted with grates and screens?			
18. Are plant facilities and equipment satisfactory with respect to absence of slime and/or mold buildup? *			
19. Are cleanup procedures adequate and supported by: *			
a. proper equipment and materials?			
b. trained and well supervised personnel?			
c. sufficient time to accomplish the work?			
20. Are blending tanks, product ingredient pipelines, pumps, and valves cleaned frequently (including dismantling if necessary)? *			
21. When overflow sirup and brine are used, are they properly handled to avoid contaminating the products? *			
22. Are window ledges, wall plates, beams, equipment, etc., free from lunch boxes, tools, and personal gear? *			

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* Answer when plant is in operation

E. PROCESSING AREA, EQUIPMENT AND FACILITIES (continued)

DEFICIENCIES

[illegible]

F. WATER SUPPLY

Municipal Private Both

	YES	NO	Rating
1. Is the plant's water supply approved by a state, municipal or private authority?			
2. If yes, name the authority.			

DEFICIENCIES

ITEM Letter And Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

G. TOILET FACILITIES

	YES	NO	Rating
1. Is there an adequate number of toilet facilities?			
2. Do toilet rooms have independent outside ventilation?			
3. Are toilet rooms designed so that they do not open directly into rooms or compartments in which processed products are being handled?			
4. Are toilet rooms equipped with self-closing doors?			
5. Are toilet rooms well lighted?			
6. Are there sufficient and proper waste receptacles?			
7. Are there signs posted indicating the importance of hand washing (multilingual if appropriate)?			
8. Do hand washing facilities include hot and cold water, soap, and individual towels or forced air hand dryers?			
9. Are toilet rooms clean, dry and of good general appearance? *			
10. Are all toilets, sinks, and faucets in good working condition? *			
11. Are waste receptacles emptied as necessary? *			

DEFICIENCIES

ITEM Letter And Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

H. WAREHOUSE AND STORAGE FACILITIES

	YES	NO	Rating
1. Is the warehouse in good repair?			
2. Are the packaging, labeling, and storage areas neat and orderly?			
3. Are empty containers protected from dust and other sources of contamination?			
4. Are materials and supplies stacked in a manner to permit sanitation inspection?			
5. Is the condition of storage areas adequate to protect the finished product, materials, and supplies from the elements?			
6. Are there adequate facilities to cool and maintain the raw product when necessary?			
7. Are there adequate facilities to refrigerate or freeze the finished product as required?			
8. Are there temperature-recording devices located in the freezer facilities?			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

I. WASTE DISPOSAL
(refers to waste areas in the plant and on plant premises)

	YES	NO	Rating
1. Is there an adequate number of waste disposal containers and are they made of materials suitable for the intended use?			
2. Are waste containers in good condition?			
3. Is the general appearance of collecting area satisfactory? *			
4. Is the frequency or removal of the waste timely? *			
5. Is drainage suitable in all area(s)? *			
6. Are waste disposal containers cleaned regularly? *			

DEFICIENCIES

ITEM Letter And Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

J. LABORATORY FACILITIES

	YES	NO	Rating
1. Is the location, size, heating, cooling, and ventilation of the laboratory sufficient to provide a good working environment for the inspectors?			
2. Is USDA-approved lighting available for color scoring?			
3. Is adequate space and inspection equipment available (including microscope and other appropriate specialized equipment)?			
4. Does the laboratory meet basic safety requirements?			
5. Are properly equipped grading stations available for line checks?			
6. Is the laboratory used only by USDA and quality control personnel?			

DEFICIENCIES

ITEM Letter And Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

K. PERSONNEL

	YES	NO	Rating
1. Do employees wear suitable clothing, including effective head coverage? *			
2. Are employees working in the processing area free from unsecured jewelry (bracelets, dangling earrings, etc.)?*			
3. Are employees working in direct contact with food, free from infected lesions or skin diseases? *			
4. Is gum chewing and all uses of tobacco limited to designated areas away from the processing areas? *			
5. Are other personal habits such that they will preclude contamination of the food? *			
6. Does plant management provide for personal comfort and assistance, such as: *			
a. A lunchroom?			
b. A first-aid station?			
c. Suitable working condition of temperature and humidity?			

DEFICIENCIES

ITEM Letter And Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

DEFICIENCIES (CONTINUATION SHEET)[illegible]

This continuation sheet may be used for any section of the plant survey.

MANDATORY CHANGES REQUIRED IF CONDITIONAL APPROVAL WAS GRANTED

[illegible]

ANNUAL SURVEY (Preliminary)

CONDUCTED BY:		APPROVED BY:	
INSPECTOR'S SIGNATURE	DATE	SUPERVISOR'S SIGNATURE	DATE

ANNUAL SURVEY (Final)

CONDUCTED BY:		APPROVED BY:	
SUPERVISOR'S SIGNATURE	DATE	OFFICER'S-IN-CHARGE SIGNATURE	DATE

(List deficiencies noted on previous survey. If corrected, note date corrected)

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APPENDIX B

**MEMORANDUM OF AGREEMENT BETWEEN THE AGRICULTURAL
MARKETING SERVICE AND THE FOOD AND DRUG
ADMINISTRATION CONCERNING THE INSPECTION AND
GRADING OF FOOD PRODUCTS 1/**

The Food and Drug Administration (FDA) of the Department of Health, Education and Welfare is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act. In fulfilling its responsibilities under the Act, FDA's activities are directed toward the protection of the public health of the nation by insuring that foods are safe and wholesome and products are honestly and informatively labeled. This is accomplished by inspecting the processing and distribution of foods and examining samples thereof to assure compliance with the Act. FDA also promulgates under the Act mandatory standards of identity, quality, and fill of container for food products after appropriate notices and hearings.

The Agricultural Marketing Service (AMS) of the U. S. Department of Agriculture, under the authority of the Agricultural Marketing Act of 1946, carries out certain voluntary service functions designed to aid in the efficient marketing of agricultural products. These include the development of commercial grade standards and specifications for foods, and furnishing inspection and grading services, including the issuance of certificates of quality and/or condition, to producers, processors, shippers, buyers, or other interested parties. The major purpose is to assist producers in preparing better quality of wholesome products and to provide objective information by means of official certification concerning the grade, quality, or condition of a product which will be of maximum assistance to all interested parties engaged in marketing functions.

The two agencies have certain related objectives in carrying out their respective regulatory and service activities. Therefore, it is believed desirable from the standpoint of public interest to set forth in this Memorandum of Agreement the working arrangements which are being followed or adopted in the interest of each agency discharging as effectively as possible its responsibilities related to inspection and standardization activities for food products.

- 1/ This Agreement does not apply to egg products, inspection of which is covered by the Egg Products Inspection Act, nor to grains, including rice, dry beans, peas, or lentils, which will be covered by a separate memorandum of agreement between AMS and FDA.

The Agricultural Marketing Service will:

1. Supply to FDA headquarters a complete list of all food processing and packing plants which are operating under AMS continuous or other resident-type inspection or grading contracts. This list will set forth the type of service provided and the food products involved. AMS will immediately advise the appropriate FDA field office of those plants subject to withdrawal or suspension of service, termination of contract or denial of inspections because of sanitation or other current good manufacturing practice deficiencies;
2. Investigate any report from FDA to the effect that a processor or packer operating under contract with AMS has not corrected objectionable conditions found to exist by FDA, and will take action in accordance with AMS regulations and contracts;
3. Decline to inspect or grade samples of products which have been seized by FDA, or which are known to be involved in formal FDA actions. This does not preclude reinspection of legally authorized samples by AMS if the FDA seizure or other actions involved products which had previously been inspected or graded by AMS;
4. Decline to assign a U. S. grade or permit the use of government official marks or other approved identification on a food product which is considered adulterated under the Federal Food, Drug, and Cosmetic Act, of such type and/or in such amounts so as to result in the food product being subject to regulatory action by FDA or is otherwise found to be not suitable for grade assignment. AMS will make such examinations and tests as are reasonably feasible for those materials and substances that would be likely to contaminate the product;
5. Report to the appropriate FDA field office information on any lot of produce which, upon inspection, AMS declines to assign a grade unless such produce is so reconditioned as to comply with FDA requirements and/or qualify for grade assignment, or is segregated and disposed of for non-food use or otherwise lawfully shipped or sold;
6. Furnish FDA headquarters, on request, with any pertinent information concerning the grade or quality determination relative to specific lots of products inspected or graded by AMS that have been proceeded against or are being considered for action by FDA;

7. Report on the inspection certificate any pertinent codes or other marks that will serve to identify the specific goods which are inspected or graded;
8. Inform FDA headquarters whenever it has information that an employee or USDA-licensed inspector is to be, or has been, subpoenaed as a witness at judicial proceedings involving FDA action and advise FDA of the nature of his proposed testimony.

The Food and Drug Administration will:

1. Recognize that the AMS service provided in connection with the voluntary contract inspection of fruit and vegetable processing establishments contributes to protection of consumers and aids FDA in enforcement of pertinent statutes. The AMS inspection service will not diminish FDA authority to inspect but should minimize FDA inspections in establishments under AMS contract inspection. In this regard, AMS inspectors will routinely advise contract establishments of pertinent FDA requirements, advise them on how to comply, and provide advice on compliance. AMS inspectors may not act as FDA inspectors but their inspections and consultations with FDA should reduce the necessity for FDA inspections;
2. Invite the AMS inspector stationed at a plant which is operating under AMS inspection to accompany the FDA inspector during his inspection of such plant. The FDA inspector will point out or discuss with the AMS inspector any conditions noted which may result in violations of the Federal Food, Drug, and Cosmetic Act;
3. Request AMS headquarters for any pertinent information concerning the grade or quality determinations relative to specific lots of products that have been proceeded against or are being considered for action by FDA and are known or believed to have been inspected by AMS. FDA will take into consideration the results of AMS inspection certificates and other available data unless it has evidence that the product does not meet legal requirements as a food or has deteriorated to such an extent, subsequent to AMS inspection, as to make it unacceptable as food;
4. Immediately notify the appropriate AMS field office concerning the details of objectionable conditions whenever such conditions are found to exist in processing or packing plants where AMS is currently conducting inspection of products, or in other food plants, when FDA believes such information would be of value to AMS in its inspection and grading activities;
5. Whenever possible, mark the claimant's samples of seized products in such a manner that AMS inspectors or graders will recognize such post-seizure samples;
6. Discuss with AMS headquarters the criteria used by FDA in order to provide the maximum assurance that AMS does not classify a food as acceptable which FDA would consider actionable under the Federal Food, Drug, and Cosmetic Act;
7. On request of AMS review labels, legends, stamps, and other official marks for products packed under the various inspection services of AMS from the standpoint of possible conflict with the misbranding provisions of the Federal Food, Drug, and Cosmetic Act.

It is mutually agreed that:

1. Both agencies will maintain close working relations with each other, both in headquarters as well as in the field;
2. Proposed regulations by either agency establishing or amending any food products standard will be referred to the other agency for review and comment prior to issuance;
3. Both agencies will cooperate jointly and with industry in the improvement of sanitation and food handling practices in processing plants. Both agencies will mutually exchange data and cooperate in the development of sampling plans, methodology, and guidelines for determining natural and unavoidable defects common to products inspected and graded by AMS;
4. Both agencies will work with industry toward greater efficiency in connection with improvement in coding methods;
5. Both agencies will cooperate in the handling of those cases of misbranding which also come under the provisions of the Perishable Agricultural Commodities Act of 1930, as amended;
6. Each agency will designate to the other a central contact point to which communications dealing with this Agreement, or matters affected thereby, may be first referred for attention;

7. Nothing in this Agreement modifies other existing agreements, nor does it preclude entering into separate agreements setting forth procedures for special programs which can be handled more efficiently and expeditiously by such special agreement;
8. The provisions of this memorandum may be modified at any time by mutual agreement.

FOR THE AGRICULTURAL MARKETING SERVICE

Date

Approved
Administrator
Agricultural Marketing Service

FOR THE FOOD AND DRUG ADMINISTRATION

Date

Approved
Commissioner
Food and Drug Administration

Effective Date. This agreement becomes effective _____ (date of publication in the FEDERAL REGISTER)
and supersedes Memorandum of Understanding dated August 28, 1973

THIS IS AN EXAMPLE OF A PLANT SURVEY LETTER

Mr. Tom Jones
Plant Manager
USDA Processing Plant
P.O. Box 123
Yakima, WA

Dear Mr. Jones:

The Processed Products Branch has completed the Plant Survey you requested covering Plant Sanitation, Facilities and Plant Operations. The plant survey at your Moses Lake facility was completed on October 6, 1993. The findings of the survey indicate the plant meets sanitation requirements in Title 21 of the Code of Federal Regulations, Part 110 for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. These regulations are published by the Food and Drug Administration.

We have attached a copy of the FV-365-1, Plant Survey for your records. Please feel free to contact our office if you have any questions or if we can be of further service to your program.

Sincerely,

Wally Supervisor
Officer-in-Charge

UNITED STATES DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
Fruit and Vegetable Division
Processed Products Branch

BRANCH NOTICE NO. 2601
December 1993

Subject: **Canadian Regulations - Plant Survey**

To: All Supervisors

Agriculture Canada, Plant Inspection, Dairy, Fruit and Vegetable Division, has amended their import regulation requirements for product being imported into Canada. The amendment requires companies to submit a completed plant survey of their facility to the Division prior to providing products for import into Canada. Agriculture Canada has requested that companies wanting to export to Canada contact the Processed Products Branch (PPB). PPB will perform a plant survey using the FV 365-1 Plant Survey form.

Attached is an example of a letter which may accompany a completed survey. If you need additional information for such a letter, please contact the regional director.

RETAIN THIS BRANCH NOTICE WITH FILE CODE 159-A-1 UNTIL FURTHER NOTICE.

James R. Rodeheaver
Branch Chief

Distribution:E
Agriculture:Washington